

**Attachment A2****510(k) Summary****1. Submitter Information****Application Correspondent**

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Date Prepared	March 4, 2011

**Applicant**

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**2. Name of Device**

Trade/Proprietary Name	HealthTracker
Product Code	DXN
Classification Panel	Cardiovascular
Regulations	Class II, 21 CFR 870.1130

**3. Predicate Device**

Trade/Proprietary Name:	Health Care System Software
Common/Usual Name:	Blood pressure test system
Submitter	TaiDoc Technology Corporation
510 (k) Number	K070941

#### 4. Device Description

The HealthTracker is an optional software accessory for use with a blood pressure monitoring system with data management capabilities. The HealthTracker transfers data from the device's memory to a computer for enhanced data management.

The proposed software includes functions of managing personal account information on computer and data upload from blood pressure monitor to a personal computer or HealthVault.

The HealthTracker is for use with BestShape Blood Pressure Monitoring System. The HealthTracker can control BestShape Blood Pressure Monitoring System in its recording of blood pressure measurements and transmitting of the data to a computer with the subject software.

#### 5. Intended Use

The HealthTracker is a software accessory for use with a blood pressure monitor with data transmission capabilities. This software is able to transfer data from the device's memory to a computer.

The HealthTracker is intended for use at home and clinical settings as an aid for users and their healthcare professionals to review, analyze and manage the historical results.

The HealthTracker is intended for use with BestShape Blood Pressure Monitoring System.

#### 6. Comparison to Predicate Device

The HealthTracker and the predicate device both use the cable connection to the personal computer and the data transferred from the device cannot be changed or modified in any way.

#### 7. Performance Studies

Risk analysis and software validation was performed to verify and validate the HealthTracker works functionally.

#### 8. Conclusion

The HealthTracker software is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

NOV 16 2011

Winstron Corporation  
c/o Ms. Teling Hsu  
TaiDoc Technology Corporation  
6th Floor, No. 127, Wugong 2nd Road  
Wugu Township, Taipei County 24888  
TAIWAN

Re: K110770  
Trade/Device Names: HealthTracker Version 1.4.3.0  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II (Two)  
Product Code: DXN  
Dated: September 27, 2011  
Received: October 17, 2011

Dear Ms. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

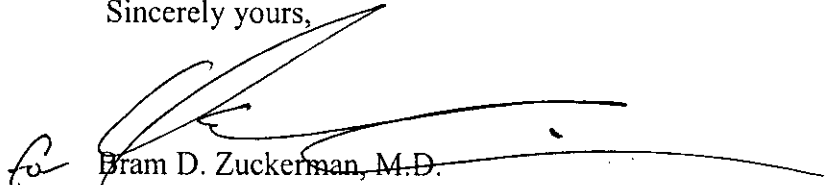
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Attachment A1**

**Indications for Use**

510(k) Number: k110770

Device Name: HealthTracker

**Indications for Use:**

The HealthTracker is a software accessory for use with a blood pressure monitor with data transmission capabilities. This software is able to transfer data from the device's memory to a computer.

The HealthTracker is intended for use at home and clinical settings as an aid for users and their healthcare professionals to review, analyze and manage the historical results.

The HealthTracker is intended for use with BestShape Blood Pressure Monitoring System.

Prescription Use \_\_\_\_\_

AND/OR

Over the Counter Use   X  

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

\_\_\_\_\_  
Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) \_\_\_\_\_

  
(Division Sign-Off)

**Division of Cardiovascular Devices**

510(k) Number   K110770  

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